

### REMARKS

Reconsideration of the present application as amended is requested. Applicants have corrected the claim numbering as indicated in the "Claim Objections" of the current office action. Applicants further appreciate the withdrawal of the rejection in based on the Biedermann publication in view of the declaration evidence.

The claims have now been rejected in view of a new combination of references, centered on U.S. patent no. 6,601,091 to Reiley and published application no. 2002/0072800 to Goble. The Reiley reference was said to disclose all the elements of independent claims 37 and 41 except for the steps related to the intervertebral disc. The Goble publication was cited as disclosing a facet joint replacement in conjunction with artificial disc replacement.

However, the Reiley reference fails to disclose deflection or deformation of the bone anchor, as required by claims 37 and 41, respectively. The facet prosthesis 330 referred to in the Office Action is shown in detail in Fig. 2. The prosthesis 330 includes a stem 310 that is positioned within the target bone. Col. 6, ll. 32-49. The stem could be in the form of the pedicle screw 310a, shown in Fig. 2a. Col. 7, ll. 1-5. The prosthesis 330 further includes a cup member 315 that is fixed to the stem 310, either by pre-welding, gluing or friction-fit. Col. 6, ll. 32-35. The cup may be provided with a surface member 325 that is fixed to the cup member 315 by adhesive, screws, nails, or friction fit or by being integrally formed with the cup. Col. 6, ll. 62-67.

There is nothing on the prosthesis 330 that can deflect or deform to permit natural motion of an intervertebral disc. Reiley specifically discloses that all of the components of the prosthesis are fixed to each other. It was suggested in the Office Action that the cup member 315 could deflect because Reiley describes the cup member as potentially being made of rubber. However, Reiley does not disclose the cup member as being deflectable, deformable or compressible. It is of course well known that some rubbers are not readily deformed, and it appears that this is the type of rubber contemplated by Reiley. All of the materials identified in the Reiley disclosure are rigid materials, such as various metals and ceramics. Moreover, the Reiley device is a facet joint replacement that relies upon sliding movement or articulation between the prosthesis 330 and the head member 510 affixed to the

lamina of the adjacent vertebra. See, Fig. 12; col. 10, ll. 7-10. A deflectable rubber component in the cup member 315 would inhibit sliding.

Reiley does not disclose any deformation or deflection between the head member 510 and cup member 315, nor would any such deformation be acceptable for a facet joint replacement. The entire object of the Reiley device is to replace a natural facet joint of the spine. This joint articulates but does not deform. Any deformation between the head 510 and cup 315 would add a degree of freedom of movement at that joint that is not part of the natural facet joint movement. This additional deformation would be detrimental and perhaps dangerous to the patient since it would create an abnormal motion of the spine at the instrumented joint that could permit one vertebra to slip relative to the other. This slippage could cause damage to the spinal cord that is in the immediate vicinity of the facet joint. Of course, Reiley certainly does not intend for the facet joint replacement to cause injury to the patient. Consequently, Reiley does not disclose or contemplate any deformation of the cup member 315, or any other element of the prosthesis 330 since such deformation would allow one vertebra to slip relative to another.

Moreover, the prosthesis 330 of Reiley is not coupled to a stabilization element, as required by claim 37. As clearly shown in Fig. 12, the head member 510 of the prosthesis 500 is not coupled to the cup member 315 (or surface member 325) of the prosthesis 330 engaged to the vertebra. As explained above, the Reiley device is an artificial facet joint which requires sliding or articulation between the head member and cup member. Col. 10, ll. 7-10. If the head member and cup member were coupled there would be no articulating joint and no movement between the adjacent vertebrae. Coupling the two components would completely destroy the essential function and purpose of the Reiley device – to emulate the movement of a natural facet joint of the spine.

Claim 41 recites coupling a dynamic stabilization system across the motion segment. The Reiley facet prosthesis cannot be coupled across the motion segment for the reasons just explained – i.e., if the prosthesis 500 is coupled to both vertebrae there would be no articulating movement between the vertebrae. Coupling a dynamic stabilization system across a motion segment would completely defeat the purpose and function of the Reiley device to act as a facet joint replacement.

Thus, the Reiley patent fails to disclose deflecting or deforming a bone anchor, as required by claims 37 and 41. Reiley further fails to disclose coupling a bone anchor to a stabilization element, as required by claim 37, or coupling a stabilization system across a motion segment, as required by claim 41. The Goble publication does not overcome these deficiencies. Like the device in Reiley, the Goble device is a facet joint replacement, so the same considerations apply that teach against a deformable or deflectable bone anchor. See, Goble, para. [0048]. Since neither Reiley nor Goble, either alone or in combination, disclose every limitation of claims 37 and 41, a prima facie case for obviousness of these claims cannot be established.

It is further noted that Applicants have amended claim 41 to clarify that the dynamic stabilization system includes at least one bone anchor engaged in each of the two vertebrae that permits natural motion of the motion segment by deforming a portion of that bone anchor. Claim 41 thus requires that a bone anchor in each of the two vertebrae deform to permit natural motion. The Reiley facet prosthesis is fixed directly to one vertebra by bilateral pedicle screws 520a, 520b, as seen in FIG. 11. See, col. 9, ll. 38-41. Reiley does not contemplate providing an articulating joint arrangement in each of the vertebrae, only in the superior vertebra, as shown in FIGS. 11-12. If an articulating joint, such as the superior facet prosthesis 330, were incorporated into the other vertebra in lieu of the pedicle screws 520a, 520b, the result would be non-functional and perhaps even dangerous to the spine. If both vertebrae in Reiley include an articulating joint, there would be nothing to prevent random movements of the two vertebrae since both vertebrae would be permitted to articulate on their respective prosthetic joint.

On the other hand, Reiley does disclose the base member 505 as being fixed to the spinous process 630 of the inferior vertebra, with the bi-lateral pedicle screws 510a, 510b being attached to the base member. If the base member 505 is already fixed to the inferior vertebra, then replacing the pedicle screws with an articulating joint would be pointless since the base member 505 cannot move relative to the vertebra to which it is fixed. Regardless of how the Reiley facet prosthesis is viewed, there is no rational basis to incorporate an articulating joint at both of the instrumented vertebrae since to do so would completely destroy the functionality and purpose of the Reiley facet joint prosthesis.

Since Reiley does not disclose or contemplate engaging a bone anchor to at least two vertebrae in which a portion of each bone anchor is deformed, Reiley cannot provide a foundation for any rejection of claim 41 as amended. The Goble reference does not overcome these deficiencies in Reiley, nor would it be expected to since the Goble device is also a facet joint prosthesis that relies on one component of the joint being fixed to one vertebra. Thus, it is believed that independent claim 41 and its dependent claims 42-47 are patentable over the art of record.

With respect to claim 46, the Reiley reference does not disclose a head portion configured for engagement to the stabilization element or a flexible portion between the head portion and engagement portion. The prosthesis 320, which is fastened to the head 315, is not engaged to the head member 510, as is clearly shown in FIG. 12. Moreover, the prosthesis 320 cannot be engaged to the head member 510, since the head member must articulate relative to the prosthesis, as explained above. Furthermore, the assumption that the head 315 is flexible because it can be made of rubber is erroneous and not supported by the Reiley disclosure. Again, if the head 315 were flexible it would permit movement in an additional degree of freedom that risks one vertebra slipping relative to the other. Moreover, a flexible head 315 would prevent the sliding or articulating movement required to emulate the natural facet joint. The addition of this degree of freedom is completely contrary to the function and purpose of the Reiley facet joint replacement. As explained above, the Goble reference also fails to disclose any flexible portion of a bone anchor. Since neither Reiley nor Goble, either alone or in combination, disclose every limitation of claim 46, a prima facie case for obviousness of this claim cannot be established.

Claim 47 was also rejected as obvious in view of the Reiley/Goble combination. Again, neither Reiley nor Goble discloses a flexible portion of the bone anchor between the head portion and the bone engaging portion, and neither reference would disclose such a structure since it would destroy their function as a facet joint replacement. Since neither Reiley nor Goble, either alone or in combination, disclose every limitation of claim 47, a prima facie case for obviousness of this claim cannot be established.

Claims 38 and 42-44 were rejected as obvious in view of the same combination of Reiley and Goble, along with patent no. 5,534,028 to Bao. Bao was cited as disclosing a

prosthetic disc nucleus having properties similar to a natural nucleus. However, the Bao reference does not disclose the structure that is missing from the Reiley and Goble references. Thus, a prima facie case for obviousness of these claims cannot be established for the same reasons set forth above with respect to independent claims 37 and 41. This same conclusion applies to dependent claims 42 and 45 which were rejected with the addition of patent no. 6,375,682 to Fleischmann. The Fleischmann reference does not account for the deficiencies in Reiley and Goble, to a prima facie case for obviousness cannot be established for claims 42 and 45.

Applicants have also added new claims 52-59, including new independent claims 52 and 54. Independent claim 52 is similar to claim 46 (which depends from claim 41) in its definition of a bone anchor having a flexible portion between the head portion and the bone engagement portion to permit deflection of the head portion relative to the engagement portion. Claim 52 is patentable over the cited references for reasons set forth above with respect to claim 46. Specifically, if the head 315 of Reiley were flexible it would permit movement in an additional unnecessary degree of freedom and would prevent the sliding or articulating movement required to emulate the natural facet joint. The addition of this degree of freedom is completely contrary to the function and purpose of the Reiley facet joint replacement. The Goble reference also fails to disclose any flexible portion of a bone anchor. Thus, neither Reiley nor the combination of Reiley with Goble recites every limitation of new independent claim 52 so this claim and its dependent claim 53 are believed to be patentable over the cited art.

New independent claim 54 is similar to independent claim 41 discussed above, except that the type of natural motion preserved by the dynamic stabilization feature is more precisely defined. In particular, claim 54 defines the natural motion as "substantially full natural rotation of the motion segment in the anterior/posterior (A/P) plane in both directions during normal flexion and extension. It is further noted that claims 54-57 are similar to claims 48-51 that were previously cancelled, with new claim 54 including additional limitations over original claim 48.

Independent claim 54 recites the step of coupling a dynamic stabilization system across the motion segment. As explained above with respect to claim 41, neither Reiley nor

Goble disclose or contemplate coupling anything across the motion segment, since to do so would prevent the normal facet joint articulation that both devices were designed to achieve. To reiterate, the purpose of both the Reiley and the Goble prostheses is to emulate the natural facet joint which requires relative sliding or articulation between adjacent vertebrae. If both the superior and inferior portions of the Reiley prosthesis were coupled to the respective vertebrae, the base member 505 would be fixed to the two vertebrae thereby eliminating any relative sliding or articulation. Thus, neither of these cited references discloses or contemplates coupling a dynamic stabilization system across a motion segment, as required by new claim 55. To the extent that the Reiley and Goble prostheses permit full natural rotation of the motion segment in both flexion and extension, they do so with only one portion of the prosthesis coupled to a vertebra, not both, as required by Applicants' claim 54.

It is therefore believed that new claim 54 and its dependent claims 55-59 are patentable over the Reiley and Goble references, whether taken alone or in combination.

It is further noted that previous claim 48 had been rejected in an earlier office action as anticipated by the published application of Ferree, No. 2003/0220643. New claim 54 differs from prior claim 48 in the recitation of "allowing substantially full natural rotation" and "during normal flexion and extension". In the prior rejection, the term "substantially" was discounted as being a broad term. It was suggested that the Ferree publication disclosed rotation of the motion segment "substantially fully in both directions" even though clear intent of the Ferree device is provided for "inhibiting full extension" and to "control spinal flexion, rotation". See, Para. 0006, l. 7 and Para.0007, l. 6. The various embodiments disclosed in Ferree specifically prevent spinal extension in order to mitigate spinal pain. See, Para. 0025, l. 11-14 ("prevents spinal extension"); Para. 0027, l. 9-11 ("prohibits extension"); Para. 0029, ll. 3-5, 9-11 ("preventing spinal extension"); Para. 0030, ll. 8-9 ("inhibits spinal extension"); Para. 0031, ll. 6-7 ("inhibits spinal extension"); Para. 0034, l. 6 ("prevent spinal extension").

There is nothing in Ferree that suggests that any embodiment permits "substantially full natural rotation ... during extension", as required by claim 54. In fact, the Ferree publication discloses exactly the opposite – the devices substantially prevent full natural rotation of the motion segment during extension. The entire object of the Ferree device is to limit the movement of the spine in a way that completely prevents spinal extension, or at best

inhibits extension. There is no way that this disclosure of Ferree can be construed as disclosing a device or method that allows "substantially full natural rotation" of a motion segment during extension. To the contrary, Ferree teaches away from Applicants' invention of claim 54 that provides a dynamic stabilization system capable of full natural rotation in both flexion and extension. It is therefore believed that new claim 54 and its dependent claims 55-59 are patentable over the previously cited Ferree reference, as well as the other references cited in the current Office Action.

With respect to new claims 58 and 59 further define the step of coupling the dynamic stabilization system to provide a center of rotation that is located substantially at the posterior surface of the pedicle (claim 58) or that is situated between the stabilization element and the normal anatomic center of rotation (claim 59). None of the cited references specifically discuss the center of rotation of the motion segment. Moreover, given the construction of the devices in Ferree, the center of rotation will be offset posteriorly from the surface of the pedicle, in the manner shown in Fig. 3 (see, CR<sub>F</sub>) and discussed at pages 3-4 of the present application. Since the Reiley and Goble devices are facet joint prosthesis, there is no discussion of center of rotation and since the devices are not coupled across the motion segment it may be assumed that the normal anatomic center of rotation is not disturbed. Thus, there is no need in Reiley or Goble to be concerned with the positioning of the center of rotation produced by the dynamic stabilization system. Since none of the cited references disclose or contemplate adjustment of the location of the center of rotation, none of these references impact the patentability of claims 58 and 59.

Applicants are submitting herewith an information disclosure statement identifying two references cited during the prosecution of a pending application related to dynamic stabilization. The Mathews reference discloses a modified bone screw, while the Berry publication discloses a facet joint replacement utilizing a ball and socket. Neither reference discloses the limitations of independent claims 37, 41, 52 or 54.

In view of the foregoing arguments it is requested that the rejections of pending claims 37-38 and 41-47 be withdrawn. It is believed that all of the claims presented in this response, namely claims 37, 38, 41-47 and 52-59, are in condition for allowance and action to that end is requested.

Respectfully Submitted,

/Michael D. Beck

Maginot, Moore & Beck, LLP  
Chase Tower  
111 Monument Circle, Suite 3250  
Indianapolis, Indiana 46204-5109  
(317) 638-2922

Michael D. Beck  
Attorney for Applicants  
Registration No. 32,722